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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/560,877	07/17/2006	Sheikh Ahmad	PC27386A	2079
23913	7590	09/26/2007	EXAMINER	
PFIZER INC			DESAI, RITA J	
Steve T. Zelson			ART UNIT	
150 EAST 42ND STREET			PAPER NUMBER	
5TH FLOOR - STOP 49			1625	
NEW YORK, NY 10017-5612			MAIL DATE	
			DELIVERY MODE	
			09/26/2007	
			PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/560,877	Applicant(s) AHMAD ET AL.	
	Examiner Rita J. Desai	Art Unit 1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>4/06</u> . | 6) <input type="checkbox"/> Other: ____ |

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DETAILED ACTION

Claims 1-11 are pending.

Claim Rejections - 35 USC § 102

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1 and 3 are rejected under 35 U.S.C. 102(a) as being anticipated by WO

01/70740 Tomasi Attilio et al

The WO '740 reference discloses the process of preparing a crystalline Form I of cabergoline. It uses toluene as a solvent and it also discloses the form V solvate formed.

See lines 16-20, page 2 of the reference.

Form I can. be readily prepared according to the present invention starting from crude material by crystallization from a toluene/diethyl ether mixture, through a new solvate form V of cabergoline. The present process for preparing

Also see lines 11-19 on page 4.

The process comprises dissolving the raw final cabergoline, obtained as an oil through the synthesis described in Eur. J. Med. Chem., 24, 421, (1989), in a suitable amount of a toluene/diethyl ether mixture,

preferably about 1:1 mixture. The resultant solution is then

cooled at a temperature of from -25° to -9°C, preferably at about -12°C for 17 hours. In these conditions, a toluene solvate is obtained, named Form V, that may be recovered by common procedures, for example by filtration under reduced

pressure or by centrifugal filtration, followed by smoothly drying of the resultant solid. The resultant crystals of

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Form V are then converted into form I upon further drying. The crystals of Form I of cabergoline prepared according to the process of the present invention have preferably a polymorph purity > 95%, more preferably >98%.

This reads on the claims 1 and 3 as applicants claims are drawn towards a process of making Cabergoline of form I from Form V by de-solvation and a drying process, wherein first the form V is formed by using a toluene as a solvent.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 01/70740 Tomasi Attilio et al further in view of WO 01/72746 Candiani et al and WO 01/72747 Tomasi et al .

Applicants claims are drawn towards a process of making Cabergoline of form I from Form V by de-solvation and a drying process, wherein first the form V is formed by using a Toluene as a solvent.

Determination of the scope and content of the prior art (MPEP §2141.01)

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The WO '740 reference teaches the process of preparing a crystalline Form I of cabergoline. It uses toluene as a solvent and it also discloses the form V solvate formed.

See lines 16-20, page 2 of the reference.

Form I can be readily prepared according to the present invention starting from crude material by crystallization from a toluene/diethyl ether mixture, through a new solvate form V of cabergoline. The present process for preparing

Also see lines 11-19 on page 4.

The process comprises dissolving the raw final cabergoline, obtained as an oil through the synthesis described in Eur. J. Med. Chem., 24, 421, (1989), in a suitable amount of a toluene/diethyl ether mixture, preferably about 1:1 mixture. The resultant solution is then cooled at a temperature of from -25° to -9°C, preferably at about -12°C for 17 hours. In these conditions, a toluene solvate is obtained, named Form V, that may be recovered by common procedures, for example by filtration under reduced pressure or by centrifugal filtration, followed by smoothly drying of the resultant solid. The resultant crystals of Form V are then converted into form I upon further drying. The crystals of Form I of cabergoline prepared according to the process of the present invention have preferably a polymorph purity > 95%, more preferably > 98%.

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

The difference is that the reference WO '740 does not specifically mention the use of heptane.

However WO 01727467 on page 8 lines 30-35 does use n-hexane as a solvent. And WO 01/72746 uses n-heptane as a to form another form of cabergoline.

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Finding of prima facie obviousness--rational and motivation (MPEP §2142-2413)

It should be noted that purification of known drugs and making different forms of known drugs is a routine experimentation for a chemist in the art. Changing solvents, temperature and pressure, pH etc to optimize results is considered to be routine experimentation and not patentable. In re Aller et al 105 USPQ 233. In re Boesch 205 USPQ 215.

Conclusion

Claims 1-11 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rita J. Desai whose telephone number is 571-272-0684. The examiner can normally be reached on Monday - Friday, flex time..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on 571-272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Rita J. Desai
Primary Examiner
Art Unit 1625

RJ Desai
9/20/07

R.D.
September 20, 2007